

## **REMARKS**

Claims 7, 9-10, 18, 25, 28-29, and 31 have been canceled without prejudice or disclaimer. Applicants reserve the right to pursue the canceled subject matter in later-filed continuing applications. Claim 1 has been amended such that the functional domain comprises the amino acid sequence of a soluble loop or strand of CCR5 (SEQ ID NO:9) and the scaffold fusion polypeptide has CCR5 activity. Support for this amendment is found throughout the specification as filed, for example, at page 20, paragraph 75 to page 22, paragraph 83. Claim 8 has been amended to depend from claim 2. In addition, claim 8 has been amended to recite “wherein said soluble loop or strand comprises the extracellular domain of CCR5.” Support for this amendment is found throughout the specification as filed, for example, at page 20, paragraph 76. Accordingly, no new matter has been introduced and the entry of the amendments is respectfully requested.

Upon entry of the present amendment, claims 1-2, 6, 8, 17, 22, 24, 26-27, and 30 will be pending. Applicants thank the Examiner for indicating the allowability of claims 26-27 and 30. The instant remarks and amendments to the claims have been made, in part, to narrow the issues for appeal that would remain in this case should the Examiner maintain his rejections in light of the amendments and remarks herein.

### **I. Claim Objections**

The Examiner has maintained the objection of claims 9 and 25 for depending upon an allegedly rejected base claim 2. Applicants believe that claims 1 and 2 are allowable and therefore the objection should be withdrawn. However, claims 9 and 25 have been canceled, thereby rendering the Examiner’s objection moot.

### **II. Claim Rejections Under 35 U.S.C. § 112**

#### **A. Enablement**

The Examiner has maintained the rejection of claims 1-2, 6-8, 17, 22, and 24 under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. In particular, the Examiner asserts that the specification, “while being enabling for *a soluble scaffolded fusion polypeptide comprising SEQ ID NO:10 and/or SEQ ID NO:31*, does not reasonably

provide enablement for *any other soluble scaffolded fusion polypeptide.*” See page 3, section 7 (emphasis in original). Moreover, the Examiner alleges that

Applicant’s amendment has failed to address the underlying problem with full enablement of the claims. This is the issue of the totality of the claims which encompass all polypeptides which contain ill-defined ‘functional domain’ and are soluble.

Page 4, sections 9-11.

Applicants respectfully disagree, and maintain that the previously pending claims were fully enabled. However, claim 17 has been canceled, thereby rendering the rejection of this claim moot. In addition, claim 1 has been amended to recite that the functional domain comprises a soluble loop or strand of CCR5, as represented by SEQ ID NO:9, and that the resulting soluble scaffolded fusion polypeptide has CCR5 activity. Thus, as discussed below, Applicants contend that the claims as amended are fully enabled by the specification as filed.

The Examiner has stated that the specification enables a scaffolded fusion polypeptide comprising the sequence disclosed in SEQ ID NOS: 10 and 31. Applicants note that SEQ ID NOS: 10 and 31, in fact, encode a specific CCR5 scaffolded fusion polypeptide, with SEQ ID NO:21 adding a signal sequence. See, e.g., Specification at paragraphs 0077 and 0148. In addition to these specific embodiments, upon reading the specification, a skilled artisan would know how to make and use any scaffolded fusion polypeptide utilizing the identified soluble loops and strands of CCR5.

In particular, the identity and function of CCR5 was well-known in the art at the time of filing. Moreover, the specification provides the sequence of CCR5 by SEQ ID number and by Genbank accession numbers (see, e.g., SEQ ID NO:9 and Genbank accession number XP\_002925.1 disclosed in the specification at paragraph 0076). In addition, the specification teaches the structural attributes of CCR5. See, e.g., paragraphs 0076-0080. Moreover, the claims have been previously amended to recite the use of only SEQ ID NOS: 6 and 7 as the scaffolding domains. Thus, contrary to the Examiner’s arguments, each domain of the claimed scaffolded fusion polypeptide indeed possess a particular conserved structure. In addition, claim 1 now requires the resulting scaffolded fusion polypeptide to possess CCR5 activity. Accordingly, based on the teachings of the specification, the skilled artisan would easily be able to choose the requisite elements, e.g.,

a soluble loop or strand of CCR5 as the functional domain, the amino acid sequence of SEQ ID NO:6 as one scaffold domain, and the amino acid sequence of SEQ ID NO:7 as the second scaffold domain, in order to make and use the scaffolded fusion polypeptides of the invention.

Based on the above, Applicants respectfully assert that the totality of the claims are fully enabled by the specification as filed. Accordingly, the enablement rejection under 35 U.S.C. § 112, first paragraph, should be reconsidered and withdrawn.

#### **B. Written Description**

The Examiner has maintained the rejection of claims 1-2, 6-8, 17, 22, and 24 under 35 U.S.C. § 112, first paragraph for alleged lack of written description. In particular, although the Examiner agrees that Applicants have adequately described SEQ ID NOs: 10 and 31, “the remaining encompassed proteins have not been adequately described in any manner as to decipher their nature, structure, function, or identity.” Page 7, section 18.

Applicants respectfully disagree, and maintain as set forth in the response submitted to the Patent Office on February 19, 2004, that the previously pending claims were fully described in the specification. However, claim 7 has been canceled, thereby rendering the rejection of this claim moot. In addition, claim 1 has been amended to recite that the functional domain comprises a soluble loop or strand of CCR5 (SEQ ID NO:9) and that the resulting scaffolded fusion polypeptide has CCR5 activity. Thus, Applicants submit that the claims as amended are clearly defined as having particular structures (*i.e.*, soluble loops or strands of CCR5 (SEQ ID NO:9) and scaffold domains comprising SEQ ID NOs: 6 and 7) and specific activities (*i.e.*, CCR5 activity), all of which are fully described in the specification as filed.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. (*See*, M.P.E.P. § 2163(I) at 2100-15, and *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991)). Thus, as noted previously, the Federal Circuit has placed the emphasize for written description on what the person of ordinary skill in the art would understand from reading the specification; and not whether the specific embodiments had been explicitly described or exemplified. Indeed, the court noted

that "the issue is whether one of skill in the art could derive the claimed ranges from the patent's disclosure." *Union Oil Company of California v. Atlantic Richfield Company*, 208 F.3d at 1001, (emphasis added).

In particular, the specification provides ample written description to enable one of skill in the art to visualize or recognize the identity of the members of the claimed genus and to assemble the claimed soluble scaffolded fusion polypeptides. For example, the specification provides the amino acid sequence of CCR5 (SEQ ID NO:9) as providing the functional domain of the claimed fusion polypeptides. *See* Specification at paragraph 0076. The specification also provides the amino acid sequence of the scaffold domains (e.g., SEQ ID NOs: 6 and 7). *See* Specification at paragraphs 0078-0079.

In addition to the amino acid sequence common to the polypeptides of the claimed invention (e.g., the functional and scaffold domains), the specification further provides ample disclosure of other relevant characteristics of the claimed polypeptides. For example, the specification discloses the structural attributes of CCR5 in that CCR5 possesses an extracellular domain, an intracellular domain, a transmembrane domain comprising seven transmembrane helices. *See* Specification at paragraph 0076-0080. The specification further describes the sequences corresponding to the scaffold domains (SEQ ID NOs: 6 and 7) as zinc binding motifs. *See* Specification at paragraphs 0058 to 0062.

Accordingly, one skilled in the art, enlightened by teachings of the present application, could readily envision the fusion polypeptide sequences that comprise the specified soluble scaffolded fusion polypeptides. Indeed, nothing more than a basic knowledge of the protein folding and what is described in the specification would be required for the skilled artisan to identify every single one of the fusion polypeptides that encompassed by the claims. Such knowledge is well within what is expected of the skilled artisan.

The instant claims clearly distinguish the boundaries of each claimed genus and identify all of the members of each genus, such that one skilled in the art, upon reading the present application as filed, would reasonably conclude that Applicants had possession of the polypeptides encompassed by the rejected claims. Accordingly, from reading the specification, the skilled person would immediately recognize that, at the time the specification was filed, the Applicants had "invented what is claimed" (*Vas-Cath*, 935

F.2d at 1563). Therefore, the specification contains an adequate written description of the claimed soluble scaffolded fusion polypeptides, and the written description rejection under 35 U.S.C. § 112, first paragraph, should be reconsidered and withdrawn.

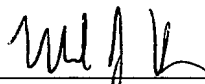
### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants believe that this application is now in condition for allowance and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the allowance of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: August 9, 2004

Respectfully submitted,

By 

Mark J. Hyman

Registration No.: 46,789  
HUMAN GENOME SCIENCES, INC.  
14200 Key West Avenue  
Rockville, Maryland 20850  
(240) 314-1224

MJH/KC/lcc